REMARKS

Claim Status:

Claims 14-18 and 29 are pending and claims 14, 18, and 29 currently amended. The original specification supports the amended claims, for example, at page 13, lines 17-18. No new matter has been added.

Priority:

The PTO alleges that the "parent application, 09/577,147, does not disclose a method of preparing an emulsion formulation comprising a thioredoxin or thioredoxin reductase, which is claimed in the instant application." Office Action of November 30, 2005, pages 2-3.

As indicated in Applicants' Response filed October 14, 2004, the present application is a continuation-in-part of U.S. Application No. **09/448,755**, filed November 24, 1999. Because the present application discloses an invention which is also disclosed in U.S. Application No. 09/488,755, the present application satisfies the conditions for receiving an earlier filing date under 35 U.S.C. § 120.

Claim Objections:

Claim 14 is objected to because of alleged language formalities. Office Action, page 3. Applicants believe the present version of claim 14 avoids the PTO's concerns.

Rejections under 35 U.S.C. § 112

Claim 29 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Office Action, page 4. Specifically, the PTO alleges that the phrase "emulsion chemically reduces a target" is unclear. *Id.* Currently amended claim 29 clarifies that the thioredoxin and thioredoxin reductase comprised in the emulsion chemically reduces a target.

Claim 29 is rejected on the grounds that the phrase "chemically reduces a target" is allegedly indefinite. Office Action, page 4. That is, the PTO alleges "it is not clear how to

differentiate an agent that reduces a target and another agent that chemically reduces a target." Id. Applicants respectfully traverse this rejection.

A claim is sufficiently definite to satisfy the statutory requirement of 35 U.S.C. § 112, second paragraph, if a skilled artisan would understand the bounds of the claim when read in light of the specification. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). Most importantly here, a claim is definite if it is amenable to construction, however confusing that task may be. *Exxon Research and Engineering Co. v. U.S.*, 265 F.3d 1375 (Fed. Cir. 2001). In other words, if the meaning of the claim is discernible, the claim avoids a rejection on indefiniteness grounds. *Id.*

In this present rejection, claim 29 is amenable to claim construction, since "reduction" is defined by dictionaries. A reduction is a chemical reaction in which a chemical substance gains electrons. *Microsoft Encarta ® World English Dictionary*, 1215 (Anne H. Soukhanov, ed., 1st ed., St. Martin's Press 2001) ("a chemical reaction that brings about an increase in electrons"). As described in the original specification, moreover, the target can be any substance susceptible to reduction, including any molecule or molecular complex (page 61, lines 16-21). Particularly susceptible targets include, for example, the disulfide bonds present in proteins.

Because the meaning of "reduction" is readily discernible, claim 29 cannot be reasonably rejected on indefiniteness grounds. Thus, the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

A. Rejection of claims 14-16, 18, and 29

Claims 14-16, 18 and 29 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Moloney *et al.*, Wieles *et al.*, and Voultoury *et a*l. Office Action, pages 5-7. Specifically, the PTO alleges "it would have been obvious to one having ordinary skill in the art to use thioredoxin or thioredoxin reductase of Wieles *et al.* in the fusion protein taught by Moloney *et al.* and formulate the fusion protein into an emulsion." Office Action, page 7. Applicants traverse this rejection.

For a proper combination of references, there must be some indicative teaching or suggestion in the prior art. MPEP § 2142. Thus, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. In fact, references cannot be combined when they teach away from their combination. MPEP § 2145X.D.

Furthermore, even if there were a suggestion that implicated such a combination, the combined teachings would not result in the claimed method. To establish a prima facie obviousness, all of the claim recitations must be taught or suggested by the prior art. MPEP § 2143.03.

Against the background of these principles, the PTO alleges "Moloney *et al.* (WO 93/21320) teach a method of making a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from a plant and a heterologous protein of interest...." Office Action, page 6. On the other hand, the PTO admits "Moloney *et al.* does not teach a method of emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase." *Id.*, second paragraph.

Yet, Moloney *et al.* fails not only to teach "emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase" but also to disclose formulating into an emultion a washed oil body preparation that comprises a "recombinant fusion polypeptide," as recited. For these reasons alone, Moloney *et al.* could not render the present invention obvious.

The PTO is understood to rely on Wieles *et al.* in an attempt to remedy the deficiencies of Moloney *et al.* According to the PTO, "Wieles *et al.* teaches polynucleotides encoding a thioredoxin and thioredoxin reductase." Office Action, page 6, paragraph 3. Like Moloney *et al.*, however, Wieles *et al.* fails to teach formulating a washed oil body preparation into an emulsion. For this reason, too, no permutation of Wieles and Moloney could render the presently claimed invention obvious. Thus, the rejection is improper and should be withdrawn.

As noted, neither Moloney *et al.* nor Wieles *et al.* suggests formulating into an emulsion a washed oil body preparation, comprising a recombinant fusion polypeptide that contains an oil body protein and a thioredoxin or thioredoxin reductase. Apparently in recognition of this fact, the PTO relies on Voultoury *et al.* (EP 0 680 751 A1), alleging that this reference teaches a method for "formulation emulsions comprising oil body proteins." Office Action, page 6, last paragraph.

In relevant part, Voultoury *et al.* discloses a method for preparing lipid vesicles from crushed seeds, wherein the oil bodies are substantially destroyed. That is, Voultoury *et al.* teaches lipid vesicles prepared from crushed seeds of an oleaginous plant, wherein the seed oil is removed to yield an oil cake, and a lipid phase is added to the oil cake to obtain a total percentage of lipids of 50-95% by weight. The oil cake and the lipid phase are then homogenized, an aqueous phase is added to the homogenized lipid phase, and an emulsion is formed. Additionally, the lipid vesicle preparation of Voultoury *et al.* uses a seed component (the oil cake) from which a substantial amount (70-90% by weight; column 1, line 37) of the oil has been removed and the oil bodies have been substantially destroyed. Additionally, the small amount of oil remaining in the oil cake is no longer present in the form of intact oil bodies.

Because the method of Voultoury *et al.* uses crushed seeds and produces substantially destroyed oil bodies, the reference neither suggests nor discloses (1) obtaining intact oil bodies and (2) washing the intact oil bodies before preparing an emulsion. For at least these reasons, Voultoury *et al.*, alone or in combination with Moloney *et al.* and Wieles *et al.*, would not render the present invention obvious.

Furthermore, and as evidenced in the as-filed application, the instant washed oil boy preparation is superior to the lipid vesicles of Voultoury *et al.* As described in Example 16, for instance, the present washed oil body displays better physical parameters (color, odor, stability) and cosmetic parameters than lipid vessicles. Specification, Example 16. That is, the intact, washed oil bodies have unexpected and improved physical and functional characteristics, compared with lipid vesicles. These improved physical and functional

characteristics make the intact, washed oil bodies more amenable for formulating into cosmetics, food, and pharmaceutical products.

Accordingly, the cited combination of references does not disclose all elements of the claims and, hence, does not establish a *prima facie* case under Section 103. For at least this reason, the rejection is improper and should be withdrawn.

B. Rejection of claim 17

Claim 17 is rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Moloney *et al.*, Wieles *et al.* and Voultoury *et al.* as applied to claims 14-16, 18, and 29 above, and further in view of Hildebrand *et al.* Office Action, page 8. Applicants respectfully traverse this rejection.

As discussed above, neither Moloney *et al.*, Wieles *et al.*, or Voultoury *et al.* teach all of the elements of the claimed invention. The PTO's reliance on Hildebrand *et al.*, to remedy the deficiencies of Moloney *et al.*, Wieles *et al.*, or Voultoury *et al.* is misplaced, however. According to the PTO, Hildebrand *et al.* discloses a method of expressing heterologous proteins in safflower cells. Office Action, page 8. Even thus characterized, Hildebrand clearly fails to teach a method for formulating and emulsifying an oil body. Accordingly, the cited references would not render the present invention obvious and the rejection should be withdrawn.

CONCLUSION

As these remarks address and avoid each rejection presented by the examiner, withdrawal of each rejection and allowance of the claims are respectfully requested.

If there are any questions concerning this application, the examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

Date February 28, 2005

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